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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,298	08/22/2003	Stefan A. Sharpe	PD06063US01	9222
24265 7590 06/27/2007 SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530			EXAMINER ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			06/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/646,298

Applicant(s)

SHARPE ET AL.

Examiner

James H. Alstrum-Acevedo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 5/30/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 21-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 21-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

**Claims 1-9 and 21-37 are pending.** Applicants previously cancelled claims 10-20. Receipt and consideration of Applicants' claim set and arguments/remarks filed on May 30, 2007 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 8-9, 21-29, 36-37 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained** for the reasons of record set forth in the office action mailed on January 30, 2007.

### ***Response to Arguments***

Applicant's arguments filed May 30, 2007 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection based on their assertions (1) that the Examiner has allegedly not read the rejected claims in light of the specification, specifically regarding the definition of a bulking agent on pages 6-7 of Applicants' specification; and (2) there are no missing elements from claims 8-9 nor 36-37, because the recited limitations are observed characteristics of the claimed compositions.

The Examiner respectfully disagrees. The specification clearly defines a bulking agent as being, "an inert substance in which or onto which the active drug ingredient(s) and excipient(s) if

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present are dispersed. The propellant, HFA 227, in the rejected claims 21-29 is an inert substance and Applicants' claimed compositions are clearly suspensions/dispersions. Thus, according to Applicants' definition of a bulking agent, HFA 227 is a bulking agent. It is immaterial whether Applicants have identified HFA 227 as also being a propellant, because Applicants' definition clearly encompasses HFA 227. Regarding claims 8-9 and 36-37, the indefinite issues specific to these claims were not explicitly addressed.

The rejection of claims 8-9 and 36-37 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn per Applicants' persuasive arguments.

#### *Response to Arguments*

Applicant's arguments, see page 7, filed May 30, 2007, with respect to the rejection of claims 8-9 and 36-37 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 8-9 and 36-37 under 35 U.S.C. 112, second paragraph has been withdrawn.

#### *Claim Rejections - 35 USC § 102*

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 6-9, 21, 26, 28-30, and 36-37 under 35 U.S.C. 102(b) as being anticipated by Fassberg (U.S. Patent No. 5,474,759) is maintained for the reasons of record.

*Response to Arguments*

Applicant's arguments filed May 30, 2007 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection based on their assertions that (1) the Examiner has allegedly not presented a case why the independent claims 1, 21, and 30 are anticipated or any basis for rejecting claims 1, 6-7, 21, 26, and 28-30 and (2) Applicants have submitted that independent claims 1, 21, and 30 are not anticipated and are in condition for allowance.

The Examiner respectfully disagrees. Regarding (1) Applicants are directed to pages 5-6 of the office action mailed on October 26, 2005, pages 5-6 of the office action mailed on June 29, 2006, and pages 4-5 of the office action mailed on January 30, 2007, where the disclosures of Fassberg were clearly set forth and explained. Applicants attention is even more expressly directed to claim 10 of Fassberg, which claims a composition comprising (i) mometasone furoate (0.01-1% w/w), which is the same active claimed by Applicants; (ii) 1,1,1,2,3,3,3-heptafluoropropane (i.e. HFA 227) (25-99.99% w/w), which is the same propellant in Applicants' claimed compositions; (iii) excipient (0-75% w/w) (i.e. excipient is optional and this reads on compositions having no excipient); and (iv) surfactant (0-3% w/w) (i.e. surfactant is optional and this reads on compositions having surfactant). Merely from the disclosure of claim 10 in Fassberg, it is readily apparent that the instant rejection is proper and Fassberg anticipates Applicants' claims. Although the disclosures of claim 10 have been reproduced above to rebut Applicants' allegations, it is noted that it is unnecessary for the Examiner to explicitly set forth a reference's disclosure in each office action. It is sufficient for the Examiner to refer Applicants to the reasons of record as has been done consistently in the prosecution of the instant

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application. It is also noted that in each and every office action the Examiner's response and rebuttal of Applicants' arguments has also been provided.

**Claims 21-26, 28-29, 31-34, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Berry et al. (U.S. Patent No. 6,068,832).**

Applicants claim a metered dose inhaler **containing** an aerosol suspension formulation consisting of an effective amount of mometasone furoate, a dry powder surfactant, and HFA 227.

Berry discloses formulations comprising **HFC 227 (i.e. HFA 227) (94.969-97.457 % w/w), mometasone furoate (0.032-0.308 % w/w), oleic acid (0.011-0.012 % w/w), and ethanol (2.492-4.985 % w/w)** (col. 5, line 45 through col. 6, line 39; claims 1, 4-7, 15-16), wherein the composition may be contained in a metered dose container **delivering a measured amount of about 10 to about 500 micrograms of mometasone furoate** from a single actuating operation. Oleic acid is inherently a dry powder surfactant, because it is the unsaturated analog of stearic acid, which Applicants explicitly claim as an example of a dry powder surfactant in claim 26.

Regarding the properties of the claimed compositions recited in claims 28-29 and 36-37, these are inherent to the compositions disclosed by Berry, because the compositions are the same. The word "containing" is treated as open claim language equivalent to "comprising,"

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-9 and 21-37 under 35 U.S.C. 103(a) as being unpatentable over Fassberg et al. (U.S. Patent No. 5,474,759) **is maintained** for the reasons of record as stated above in the instant office action.

### ***Response to Arguments***

Applicant's arguments filed May 30, 2007 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by alleging that (1) the present

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rejection and reference to prior office actions is deficient and unacceptable; and (2) the phrase “free of the carrier” has been removed from the pending claims and this change has allegedly provided novelty and unobviousness to the rejected claims. Applicants stated that they were confused and curious as to what was meant by the phrase “In favor of compact prosecution and in anticipation of Applicants’ future claim amendments.”

The Examiner respectfully disagrees with Applicants’ traversal arguments. Regarding Applicants’ confusion and curiosity concerning the meaning of the phrase “In favor of compact prosecution and in anticipation of Applicants’ future claim amendments” in the office action mailed on January 30, 2007,” this phrase clearly means that the Examiner had an expectation that Applicants might amend the rejected claims in some unspecified manner to overcome the anticipatory rejection. It is also clear from this statement, that a rejection under 35 U.S.C. 103(a) was made to expedite prosecution if Applicants had amended the rejected claims.

As described above in the previous rejection under 35 U.S.C. 102(b) based on the Fassberg reference, Fassberg clearly teaches all the limitations of Applicants’ claims. Despite removal of the phrase “free of a carrier”, Fassberg continues to obviate the rejected claims. Regarding the phrase, “free of a bulking agent”, it is noted that this phrase is defined by Applicants in the exact same manner as the phrase “free of a carrier.” Thus, these two phrases according to Applicants’ specification are equivalent and interchangeable. The instant rejection remains proper.

The rejection of claims 21-26 and 28-29 under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (WO 99/51205) in view of Kaplan et al. (U.S. Patent Application



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2002/0076382 A1) **is maintained** for the reasons of record as stated above in the instant office action.

### ***Response to Arguments***

Applicant's arguments filed May 30, 2007 have been fully considered but they are not persuasive. Applicants have not submitted any substantive arguments as to why the instant rejection is allegedly inappropriate or incorrect. Applicants have broadly asserted that the instant rejection is improper because reference to reasons already of record is allegedly improper and unacceptable.

The Examiner respectfully disagrees. The teachings of Kaplan and Dickinson have already been explicitly set forth on the record on pages 7-11 of the office action mailed on October 26, 2005. Applicants have received a copy of this office action. Thus, it is unnecessary to set forth anew in each office action the teachings of these references as Applicants imply is necessary. It is also noted that the phrase "free of a bulking agent" in rejected claims 21-26 and 28-29 is equivalent to the phrase "free of a carrier", is indefinite, and has been given no patentable weight for determination of prior art. Therefore the Examiner concludes that a person of ordinary skill in the art would have found that claims 21-26, and 28-29 are *prima facie* obvious over the combined teachings/disclosures of Dickinson and Kaplan because each and every element of the claimed MDIs is taught explicitly or implicitly by the prior art and is thus rendered obvious.

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The rejection of claims 1-6 and 8-2 under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (WO 99/51205) in view of Kaplan et al. (U.S. Patent Application 2002/0076382 A1) **is withdrawn** per Applicants use of "consisting of" language.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-5, 7, and 13-18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,474,759 **is maintained**, for the reasons of record on pages 11-12 of the office action mailed on October 26, 2005.

The rejection of claims 1, 2-5, and 13-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 10, and 12 of copending Application No. 10/967,719 (copending '719) in view of Kaplan et al. (U.S. Patent Application US2002/0076382) **is maintained** for the reasons of record on pages 12-14 of the office action mailed on October 26, 2005.

The rejection of claims 1, 10, and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-7 of copending Application No. 10/649,398 (copending '398) **is maintained** for the reasons of record on pages 14-16 of the office action mailed on October 26, 2005.

The provisional rejection on the ground of nonstatutory obviousness-type double patenting of claims 1-9 as being unpatentable over claims 1-9 and 20-26 of copending Application No. 11/071,078 (copending '078) in view of García-Marcos et al. **is maintained** for the reasons of record set forth on pages 4-5 of the office action mailed on June 29, 2006.

#### ***Response to Arguments***

Applicant's arguments filed May 30, 2007 have been fully considered but they are not persuasive. **Applicants have submitted no substantive arguments** as to why the above rejections on the ground of nonstatutory obviousness-type double patenting are allegedly inappropriate or incorrect. The mere statement of Applicants' belief that the amendments and new claims are allowable is not a persuasive argument. Therefore the Examiner concludes that above obviousness-type double patenting rejections (provisional and non-provisional) remain proper.

**Claims 21-26, 28-29, 31-34, and 36-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-16 of U.S. Patent No. 6,068,832 (USPN '832). Although the conflicting claims are not identical, they are not**

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**patentably distinct from each other because these are substantially similar and/or mutually obvious.** Applicants' claims have been described above. Independent claim 15 of USPN '832 claims a metered dose inhaler comprising an aerosol suspension comprising 1,1,1,2,3,3,3-heptafluoropropane (i.e. HFA 227), about 1 to about 10 % w/w ethanol, micronized mometasone furoate, and optionally a surfactant. Applicants' claims utilize open claim language, thus the inclusion of ethanol in the claims of USPN '832 is not a distinguishing feature and merely represents an obvious variation of the compositions claimed by Applicants. Therefore, the Examiner concludes that a person of ordinary skill in the art would have found that claims 21-26, 28-29, 31-34, and 36-37 are *prima facie* obvious over claims 15-16 of U.S. Patent No. 6,068,832 (USPN '832).

### ***Conclusion***

**Claims 1-9 and 21-37 are rejected. No claims are allowed.**

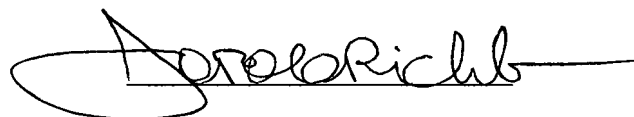
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo  
Patent Examiner  
Technology Center 1600

A handwritten signature in black ink, appearing to read "Johann R. Richter", with a large, stylized loop at the beginning and a horizontal line extending to the right.

Johann R. Richter  
Supervisory Patent Examiner  
Technology Center 1600